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July 25, 2003

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Via Hand Carry to Examiner James S. Ketter Art Unit 1636

Re:

U.S. Utility Patent Application

Appl. No. 09/732,914; Filed: December 11, 2000 Use of Multiple Recombination Sites with

Unique Specificity in Recombinational Cloning

Inventors:

CHEO et al.

Our Ref:

0942.5010002/RWE/BJD/JKM

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Fifth Supplemental Information Disclosure Statement;
- List of cited references on Form PTO-1449 (8 sheets); 2.
- 3. A copy of each reference cited on Form PTO-1449 (25 documents: AK6-AB7, and AT103-AT110); and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents July 25, 2003 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono

Attorney for Applicants

Registration No. 42,473

RWE/BJD/JKM/acr Enclosures

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Sterne, Kessler, Goldstein & Fox P.L.C.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CHEO et al.

Appl. No. 09/732,914

Filed: December 11, 2000

For: Usa

Use of Multiple Recombination Sites with Unique Specificity in

Recombinational Cloning

Confirmation No. 2341

Art Unit:

1636

Examiner:

Ketter, James S.

Atty. Docket: 0942.5010002/RWE/BJD/JKM

D: 31

Fifth Supplemental Information Disclosure Statement

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fifth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fourth Supplemental Information Disclosure Statement filed on May 8, 2003, in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Fifth Supplemental Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

Date: July 25, 2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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	AS	104	Brent, R., an gene,* Natur	Brent, R., and Ptashne, M., "A bacterial repressor protein or a yeast transcriptional terminator can block upstream activation of a yeast gene," <i>Nature 312</i> : 612-615, Macmillan Journals Ltd. (1984).								
	AT	104	Cherapanov excision of the	, P.P., and Wackernage ne antibiotic-resistance	el, W., "Gene disruption in <i>Escl</i> determinant," <i>Gene 158</i> : 9-14,	<i>herichia coli</i> : Tc ^R and Elsevier Science B.\	Km ^R cass /. (1995).	ettes with the optic	on of Flp-catalyzed			
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	AS 106 CLONTECH, *Creator™ SMART™ Lib				ibrar	ary Construction Kit, * CLONTECHniques 16:2 pages, CLONTECH (October 2001).						
	AT	<u>106</u>	CLONTECH, "C 2001), available	Creator™: The Univers e at http://www.clontec	sal P	latform for Analysis of Gene Function," Pow m/products/families/creator/popups/s1page	verpoii 1.html	nt Present	ation, pp. 1-9, CL	ONTECH (July 24,		
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	AS	<u>107</u>	CLONTECH, *New Creator™ -Compatible Expression Systems,* CLONTECHniques 15:2 pages, CLONTECH (October									
	AT	<u>107</u>	Enquist, L.W., a Bacteriophage I	and Weisberg, R.A., "The Lambda," <i>Virology</i> 72: 1	e Re 47-1	ed Plaque Test: A Rapid Method for Identifi 153, Academic Press, Inc. (1976).	cation	of Excision	on Defective Vari	ants of		
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	AS	108	Klippel, A. et al., *Isolation and characterization of unusual gin mutants,* The EMBO Journal 7: 3983-3989, IRL Pre							Inc. (1988).		
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	AS	<u>109</u>	Okayama, H., an Cellular Biology	Okayama, H., and Berg, P., *Bacteriophage Lambda Vector for Transducing a cDNA Clone Library into Mammalian Cells,* <i>Molecular and Cellular Biology</i> 5: 1136-1142, American Society for Microbiology (1985).								
	AT	<u>109</u>	Sauer, B., *Expre (I340), Alan R. Li	Sauer, B., "Expression and Functioning in Yeast of a Bacterial Site Specific Recombination System," J. Cell. Bio. Chem. Supp. 10(b): 242 (1340), Alan R. Liss, Inc. (1986).								
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	AS	110	Scott, S.D., and Macmillan Publis	Scott, S.D., and Marples, B., *Comment on the use of the cre/loxp recombinase system for gene therapy vectors,* <i>Gene Therapy 7</i> : 1706, Macmillan Publishers Ltd. (2000).								
	AT	<u>110</u>	Vetter, D. et al., Sciences (1983).	/etter, D. et al., "Site-specific recombination of yeast 2-μm DNA in vitro," Proc. Natl. Acad. Sci. USA 80: 7284-7288, National Academy of Sciences (1983).								
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